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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/04/2002

Timothy M Murphy
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EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 09/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/720,952

Applicant(s)

GRAHEK ET AL.

Examiner

Golam M M Shameem

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendment filed by applicant in paper No. 6, dated May 31, 2002, which has been entered in the file.

Status of Claims

Claims 1-27 are pending in this application.

Response to Arguments

Claims 1-27 (originally 1-25) are rejected under 35 U.S.C. §103(a) as being unpatentable over Haytko et al (US Pat No 5,202,029) of record and the rejection has been maintained for the reasons set forth in paper No. 4. Applicant's arguments have been considered but are not deemed persuasive for the following reasons.

In response to applicant's argument that the skilled person would not contemplate a purification technique which is basically different from the pertinent prior art, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ 2nd 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2nd 1941 (Fed. Cir. 1992). Additionally, the disclosure by Horvath, C. (J. Chromatography Library) necessitates a new ground of rejection.

Applicant's arguments are found sufficient enough to overcome the rejection of claims 1-25 under 35 USC § 112 second paragraph for the reasons set forth in paper No.

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4. The rejection of claims has been obviated and the Examiner regrets any inconvenience that this may have caused.

Authorization for the Examiner's amendment was given in a telephone interview with Mr. Timothy Murphy on July 9, 2002. Claims 1, 4 and 6 are amended (to replace "includes" with consists of).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haytko et al (US Pat No 5,202,029) in view of Horvath, C. (J. Chromatography Library). Applicant claims a process for obtaining HMG-CoA reductase inhibitors of high purity.

Determination of the scope and content of the prior art (MPEP §2141.01)

Haytko et al teach a generic process for the purification of an HMG-CoA reductase inhibitor employing preparative high performance liquid chromatography.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The process taught by Haytko et al are similar processes of applicant's claims. The difference between the process taught in the reference and the claimed process herein lie in that the instant invention use displacement chromatography tool instead of high performance liquid chromatography (HPLC) for the purification purpose of the same compounds. Although Haytko et al is silent about the use of the displacer such as long

chain alcohols, however in analogous art Horvath et al teach that the term chromatography (HPLC and displacement) has become synonymous (see page 179, lines 1-4, also whole article). It is obvious to purify compounds by a similar chromatography technique in the absence of any unobvious or unexpected results.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One having ordinary skill in the art would find the claimed process prima facie **because** one in possession of the above reference would be motivated to employ displacement chromatography technique for the purification process knowing that such modification would be operable to obtain similar yields of product. Since there is an exemplary teaching of a process to obtain the claimed compounds in the prior art, one would have reasonable expectation that such replacement of technique would give compounds with similar rate of recovery. Applicants should note that a generic teaching is grounds for obvious type of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (703) 305-0116. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703) 308-4532. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other


communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

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Patent Examiner
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August 25, 2002


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